IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Franco Vallana et al. Attorney Docket: SBC1025USC1

Serial No.: To Be Assigned <u>Prior Application</u>:

Group Art Unit: 3738

Filed: Herewith Examiner: Suzette Jamie Jackson

Title: ANGIOPLASTY STENTS

COMMUNICATION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

REMARKS

The differences between this application and the parent application as originally filed are described below.

At page 1, after the title, the following paragraph was added:

--This application is a continuation of U.S. Serial No. 10/198,054 filed July 18, 2002, now U.S. Patent No. 6,699,281.--

At page 4, line 16, "extends" was changed to read --extend--.

At page 12, line 20, "Figure 4" was changed to read -- Figure 5--.

At page 12, line 29, the following paragraph was added:

--Figure 10A is a partial schematic view of a stent of this invention, in which a plurality of annular elements 2 having a roughly cylindrical shape and a

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VA 22313-1450 on the date indicated below.

Signature:

Name: Jodi Jang

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serpentine pattern are designed to be aligned in sequence along the main axis of the stent designated as the Z axis.--

At page 15, line 20, "24000" was changed to read --2400--.

The change at page 1 adds reference to the prior co-pending parent application. The change at page 4 is grammatical. The change at page 12 corrects an obvious error; Figure 5, not Figure 4 shows the neointima structure, NI. The change at page 12 responds to the Examiner's request in the parent application, U.S. Ser. No. 10/198,054, to describe Figure 10A. The change at page 15 corrects an obvious error; the recesses in Examples 1 and 2 each receive the same quantity of active substance, 2400 square microns. All these changes except for the ones made to pages 1 and 4 were entered in the parent application.

In an Office Action mailed August 15, 2003, in the parent application Serial No. 10/198,054, the Examiner objected to the originally filed drawings for failing to show the element "O" described in the specification on page 7, line 21. The enclosed drawings of Figures 2 and 4 include element "O". These drawings were entered in the parent application.

The enclosed claims were generated by canceling claims 10, 13, 14, 28, 31 and 32 of the parent application and renumbering the claims appropriately.

This application is a continuation of U.S. Serial No. 10/198,054, filed July 18, 2002, which will issue as U.S. Patent No. 6,699,281 on March 2, 2004. The following remarks are responsive to an Office Action mailed August 15, 2003, in parent application Ser. No. 10/198,054 rejecting the presently pending claims.

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Rejection over Harish and von Oepen

Claims 1-4, 6-8, 11, 12, 15-21, 25, 26, 29, 30, and 33-37 (now claims 1-4, 6-8, 10, 11, 12-18, 22, 23, 25, 26, and 27-31) were rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Pat. No. 6,506,437 (Harish) in view of U.S. Pat. No. 6,193,747 (von Oepen).

Applicants traverse this ground of rejection. Harish and von Oepen, taken separately, together or combined with any record references, do not render the present claims obvious. Claims 1, 17, 35, and 37 (now claim 1, 14, 29, and 31) are independent.

Claim 1 requires that the active-agent-containing recesses are positioned only in rectilinear portions of the stent. Harish is said to disclose stents with active agents contained in recesses/depots (28) on the stent exterior where the stent can be of any design (Harish, col. 3, lines 60-63; col. 4, lines 42-43). Von Oepen is said to teach the present stent structure (Fig. 2B). From Figs. 3A and 3B of Harish, one of skill in this art will recognize that the depots/recesses 28 are positioned on the struts 24 that are curved, not rectilinear. Nothing in Harish or von Oepen shows or suggests positioning the recesses on only rectilinear portions of the stent, as required by claim 1. Harish goes on to state, "[d]epots 28 ... can be formed in virtually any implantable device 10 structure at any preselected location within implantable device 10" (col. 4, lines 44-52).

Claim 17 (now claim 14) requires that the geometry of the active-agent-containing recesses is such that bending moments of inertia of the stent elements containing the recesses are not substantially reduced. Claims 35 and 37 require that the geometry of the recesses be such that the bending strength of the recess containing portions is not substantially reduced. Harish and von Oepen are silent on any teaching or suggestion that the geometry of the recesses should be such that

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bending moments of inertia of the stent elements containing the recesses or that the bending strength of the recess containing stent portions are not substantially reduced, as required by claims 17, 35, and 37 (now claims 14, 29, and 31).

Claim 35 (now claim 29) requires that the active-agent-containing recesses are positioned only in stent portions that are not subject to stress during expansion or use of the stent. Claim 37 (now claim 31) requires that the active-agent-containing recesses are positioned only in stent elements that are not subject to deformation. From Figs. 3A and 3B of Harish, one skilled in this art will recognize that the depots/recesses 28 are positioned in struts 24 that are subject to stress and deformation during stent expansion or use, contrary to the requirements of claims 35 and 37. Nothing in Harish or von Oepen shows or suggests positioning the recesses on only stent portions not subject to stress and deformation during stent expansion or use.

The dependent claims 2-4, 6-8, 11, 12, 15, 16, 18-21, 25, 26, 29, 30, 33, 34, and 36 (now claims 2-4, 6-8, 10-13, 15-18, 22, 23, 25-28, and 30) add further structural limitations to the independent claims and constitute unique combinations that are allowable over Harish and von Oepen.

Rejection over Harish, von Oepen and Hossainy

Claims 5, 9, 22-24 (not 23-23 as indicated in the August 15, 2003 Office Action in Ser. No. 10/198,054) and 27 (now claims 5, 9, 19-21, and 24) are rejected under 35 U.S.C. 103(a) as unpatentable over Harish in view of von Oepen and further in view of U.S. Pat. No. 6,379,381, Hossainy.

Applicants traverse this ground of rejection. The remarks made above regarding Harish and von Oepen are repeated here as equally pertinent. Hossainy has no teaching or suggestion, alone or combined with any other record references,

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that renders obvious the present claims. Hossainy is said to teach an implantable prosthesis with rectangular and undercut shapes (Hossainy, Fig. 3a and 3b). Figs 1 and 2 of Hossainy are the same as Figs. 3A and 3B of Harish and the remarks made above regarding Harish and these figures are repeated here as equally pertinent. Hossainy actually teaches away from the present invention in stating (col. 4, lines 45-52):

The locations of depots 22 vary according to the intended usage and application of stent 10. Depots 22 are formed by a manufacturer at any preselected location and have any preselected depth, size, and geometrical configuration. In one example, depots 22 are evenly distributed through body 16 and have an equal volume so that the tissue in contact with stent 10 receives an equal distribution of a therapeutic substance.

Thus, Hossainy, taken alone or with any other record references, offers no teaching or suggestion regarding the specific characteristics of the stents of the present claims. The dependent claims 5, 9, 22-24 and 27 (now claims 5, 9, 19-21, and 24) add further structural limitations to the independent claims and constitute unique combinations that are allowable over Harish, von Oepen, Hossainy and the other record references.

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Conclusion

All of the rejections and objections of record in the parent application have been overcome. A Notice of Allowance is solicited. Should any minor matters remain before allowance of this application, the Examiner is requested to telephone Terry L. Wiles to achieve prompt resolution thereof.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: 3/1/04

 $By_{_}$

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